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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 01/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/767,067

Applicant(s)

WEINBERGER, PEDRO J.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7 and 20 is/are allowed.
- 6) ☒ Claim(s) 6, 8-19, 21-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claims 6, 12, 16, 25, and 29 is withdrawn in light of the claim amendments.
3. The rejection of claims 1-32 under the judicially created doctrine of obviousness-type double patenting is withdrawn in light of the claim amendments.
4. The rejection of claims 1-32 under 35 U.S.C. 102(e)/103(a) is withdrawn in light of the claim amendments.

Specification

5. The specification remains objected to for the reasons of record stated in the Office action mailed 07 August 2002 under item 1. Applicants traverse the rejection in the paper received 07 November 2002. Applicant's arguments have been fully considered but were not found persuasive.

Applicant argues that the specification will be amended to contain the accession number of the ATCC deposit of seed of 39K40 (response, page 8, 2nd paragraph). However, the blank lines on page 7 of the specification are the locations that should recite the ATCC deposit

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numbers of Pioneer Hi-bred proprietary inbred lines that were crossed to produce 39K40, not for 39K40 itself. Applicants have not provided any assurances regarding the deposit of the inbred lines.

Claim Rejections - 35 USC § 112

6. Claims 6, 8, 11, 15, 19, 21, 28, and 32 remain and new claims 33, 34, and 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record stated in the Office action mailed 07 August 2002 under item 4. Applicant traverses the rejection in the paper received 07 November 2002. Applicant's arguments were fully considered but were not found fully persuasive.

Regarding the indefinite issue of the recitation "39K40": Applicants provide assurance that seed of corn plant 39K40 will be deposited with the ATCC, and that the deposit number will be inserted into the claims, upon receipt of a notice of allowable claims (response, page 10, 1st full paragraph). This assurance satisfies the issue concerning the recitation "39K40." However, the rejection is applied to new claim 33, as it refers to two other corn plants, GE535658 and GE516223. No assurances have been provided concerning their ATCC deposits.

Regarding the indefinite issue concerning the relative terms in claims 11, 15, 19, 24, 28, and 32: Applicant argues that each of the claims recites two requirements: that 39K40 be an ancestor of the plant, and that the claimed plant be "capable of expressing a combination of at least two 39K40 traits" selected from a Markush grouping (response, paragraph bridging pages 10-11). However, this issue was not raised in this rejection. Applicant also argues that the

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terminology of the adjectives is well known in the art and would be understood by one skilled in the art. Applicant argues that the terminology of the adjectives is not unduly narrative and or imprecise as they characterize and positively recite the degree of expression of the particular traits within Tables 1-4 (response, paragraph bridging pages 10-11). However, the specification does not teach that the traits in Tables 1-4 can be described in the manner in the claims. The specification does not define the separation from very good early growth, for example, from good early growth or outstanding early growth.

Applicant argues that the claims now indicate that the plants have 50% of the alleles of 39K40, and that the plants be able to express a combination of two traits of 39K40 (response, paragraph bridging pages 10-11). However, the recitation of "50% of its alleles" does not affect the issue raised in this rejection. That the claimed plants are to express a combination of two traits that are also expressed by 39K40 also does not overcome the rejection, as it is not clear what separates a plant having, for example, very high yield from good yield. Applicants also argue that it is against the policy of the patent statutes to bar patent protection for inventions that are incapable of precise definition and assert that the terms in the claims are as precise as the subject matter of the invention permits (response, page 11, 1st full paragraph). However, it remains unclear how one would differentiate, for example, very good stalks from exceptional stalks.

In claim 6: there is improper antecedent basis for "protoplasts" in line 1. It is suggested that the term be removed from the claim, and that a new claim be introduced directed towards protoplasts produced from the tissue culture of claim 5.

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In claims 8 and 21: the recitation “genetic factor” renders the claims indefinite. It is not clear what is encompassed by the term “factor.” It is suggested that “genetic factor conferring” be replaced with --transgene encoding a product that confers--.

In claims 11, 15, 19, 24, 28, 32, 38, and 39: the recitations “has derived at least 50% of its alleles” in claims 11, 15, 19, 24, 28, and 32, and “deriving at least 50% of its alleles” in claims 38 and 39 render the claims indefinite. It is not clear what is meant by “derived” and “deriving.” Have the alleles been transformed into the claimed plants, did the claimed plants inherit the alleles in crosses, etc.?

In claim 33: the recitation “developing from the cross a hybrid maize plant” in line 4 renders the claim indefinite. The claim does not clearly indicate that the hybrid maize plant in the recitation is the same as 39K40, mentioned in line 1. It is suggested that in line 4, “a” be replaced with --said--.

In claim 34: the recitation “essentially” in line 3 renders the claim indefinite. It is not clear what is encompassed by the term. The recitation makes the metes and bounds of the claim unclear.

In claim 38: the recitation “on average, deriving at least 50%” in line 2 renders the claim indefinite. It is not clear what is being referred to by this recitation. The metes and bounds of the claim are not clear.

In claim 39: the recitation “A 39K40 maize plant selected from the population of 39K40 progeny maize plants” renders the claim indefinite. The claim is drawn to plant 39K40, yet can comprise less than 100% of the alleles of 39K40.

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In claim 40: the recitation “further comprising applying double haploid methods” renders the claim indefinite. The recitation broadens the scope of parent claim 37, which only involves crosses and does not encompass any double haploid method. It is also not clear what double haploid method is being referred to.

7. Claims 11-19, and 24-32 remain and claims 9, 10, 22, 23, 34-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 07 August 2002 under item 5. Applicant traverses the rejection in the paper received 07 November 2002. Applicant’s arguments have been fully considered but were not found fully persuasive.

Applicant argues that the claim amendments overcome the rejection for claims 8 and 21 (response, page 13, 1st full paragraph). The amendments overcome the written description issue raised for these claims, and the rejection is withdrawn from claims 8 and 21.

Applicant argues that the claims have been amended by adding the threshold, having 50% of the ancestral alleles, that limits the variation permitted among the genus, as well as an assayable function, capable of expressing a combination of at least two traits of 39K40. Applicant argues that in plants, identifying characteristics are those detectable in the phenotype, which is manifested through gene expression, and that claims to a particular species of invention are adequately described if the disclosure of relevant identifying characteristics is present in the application. Applicants argue that one of ordinary skill is reasonably apprised in knowing that a

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plant crossed with 39K40 will result in a plant having half the genetic contribution of 39K40, and that a further limitation set is that the plants must be capable of expressing a combination of at least two phenotypic characteristics of 39K40 (response, paragraph bridging pages 13-14). However, the specification does not provide a description of the alleles of 39K40, nor does it describe the functions that are associated with each of the alleles of 39K40. The specification does not describe the alleles that govern the expression of any of the traits listed in the claims. As the alleles of 39K40 are not described, neither are the alleles of its descendants. Further, the new claims encompass plants that can express any traits, none of which are described. Furtherstill, no description of any trait is provided concerning the other parents of the claimed plants. 50% of the alleles of the claimed plants will also be inherited from the other parent, for which no description is provided.

Applicant also argues that the specification supplies an extensive definition and description of "transgene" and transgenes of interest. Applicant argues that the trivial modification introduced by the transgenes to 39K40 are clearly supported and described in the present application (response, paragraph bridging pages 14-15). However, as written, the claims encompass any and all transgenes, even those that have yet to be isolated and for which descriptions are unknown. Further, the effect that a transgene can have on its host plant depends on the function of its encoded product, among other considerations, and the modification cannot simply be described as "trivial." A transgene that is a transcription factor, for example, could effect the expression of numerous genes and phenotypes. It is suggested that claims 12 and 25 be amended by listing the types of transgenes that may be introduced, provided that the

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specification or the prior art indicates that the gene has been isolated, for example genes that confer resistance to a plant virus.

Applicants also argue that the claims are definite (response, page 15, 2nd full paragraph). However, definiteness of the claims is not the issue of this rejection.

Further, the specification does not describe any traits of any inbred plants or any progeny plants produced from 39K40, nor does it mention any double haploid method. While plants produced by self or sib pollinating 39K40 would inherit all of their alleles from 39K40, the morphological and physiological characteristics of the progeny plants would be different from those of 39K40, as the genotype of the progeny would not be the same as that of hybrid 39K40.

8. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed 07 August 2002 under item 6 for claims 1-32. Applicant traverses the rejection in the paper filed 07 November 2002. Applicant's arguments have been fully considered and found persuasive for claims 1-32. However, Applicant's arguments were not persuasive for new claim 33.

The claim is drawn towards a method of making a hybrid plant designated 39K40 comprising crossing inbred maize plant GE516223 and GE535658.

Applicant has provided assurance that the seed of hybrid 39K40 will be deposited with the ATCC, and that the application will be amended to recite the assigned ATCC accession number, upon receipt of a notice of allowance (response, page 16, 1st full paragraph). The

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rejection is withdrawn from claims 1-32 in light of this assurance and in accordance with MPEP 2411.02.

However, lines GE516223 and GE535658 are essential to claim 33. These lines do not appear to be readily available to the public, as they are proprietary lines, and their deposits are required.

9. Claims 1-5, 7, and 20 are allowed. Claims 6, 8-19, and 21-40 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 6, 2003



**ASHWIN D. MEHTA, PH.D
PATENT EXAMINER**